

## CLAIMS

Having thus described the invention, what is claimed is:

1. A method for distinguishing irritable bowel syndrome from inflammatory bowel disease, the method comprising:

5 obtaining a fecal sample from a person to be diagnosed; and

determining whether said sample contains an elevated level of endogenous lactoferrin, wherein if said sample does contain an elevated level of endogenous lactoferrin, diagnoses of irritable bowel syndrome and other noninflammatory etiologies are substantially precluded.

10 2. The method as recited in claim 1, further comprising diluting said fecal sample.

3. The method as recited in claim 2, wherein said step of diluting said fecal sample comprises diluting said sample to a 1:400 dilution factor.

15 4. The method as recited in claim 1, wherein said endogenous lactoferrin comprises total lactoferrin from one or more of plasma, <sup>IN</sup> bile, leukocytes and mucosal secretions.

5. The method as recited in claim 1, wherein said endogenous lactoferrin is qualitatively determined.

20 6. The method as recited in claim 1, wherein said step of determining whether said sample contains an elevated level of endogenous lactoferrin includes contacting said sample with immobilized polyclonal antibodies to human lactoferrin to create a treated sample.

*relative  
what  
treatment*

7. The method as recited in claim 6, wherein said step of determining whether said sample contains an elevated level of endogenous lactoferrin further includes contacting said treated sample with enzyme-linked polyclonal antibodies to create a readable sample.

8. The method as recited in claim 7, wherein said step of determining whether said sample contains an elevated level of endogenous lactoferrin further includes determining an optical density of said readable sample at 450 nm, wherein said optical density corresponds to a level of endogenous lactoferrin in the sample.

9. The method as recited in claim 8, wherein if said optical density of said readable sample is greater than 0.200, said fecal sample contains an elevated level of endogenous lactoferrin.

10. An assay for determining the concentration of endogenous lactoferrin, said assay comprising:

obtaining a human fecal sample;

diluting said fecal sample;

contacting said sample with immobilized polyclonal antibodies to endogenous lactoferrin to create a treated sample;

contacting said treated sample with enzyme-linked polyclonal antibodies to create a readable sample;

determining the optical density of said readable sample at 450 nm;

generating a purified lactoferrin standard curve; and

comparing said optical density of said readable sample to said standard curve to determine the concentration of endogenous lactoferrin in said fecal sample.

11. The assay as recited in claim 10, wherein said step of diluting said fecal sample comprises diluting said sample by serial ten-fold dilutions.

12. A diagnostic assay for differentiating irritable bowel syndrome from inflammatory bowel disease by determining the level of endogenous lactoferrin, said assay comprising:

obtaining a human fecal sample;

diluting said sample;

contacting said sample with immobilized polyclonal antibodies to endogenous lactoferrin to create a treated sample;

contacting said treated sample with enzyme-linked polyclonal antibodies to create a readable sample; and

determining the optical density of said readable sample at 450 nm to determine whether said readable sample contains an elevated level of endogenous lactoferrin as compared to a reference value for healthy control subjects.

13. The diagnostic assay as recited in claim 12, wherein if said readable sample contains an elevated level of endogenous lactoferrin, a diagnosis of irritable bowel syndrome is substantially precluded.

14. The diagnostic assay as recited in claim 13, wherein if said optical density of said readable sample is greater than or equal to 0.200, said fecal sample contains an elevated level of endogenous lactoferrin as compared to a reference value for healthy control subjects.

15. The diagnostic assay as recited in claim 12, wherein said assay comprises an enzyme-linked immunoassay.

16. The diagnostic assay as recited in claim 12, wherein said endogenous lactoferrin comprises total lactoferrin from one or more of plasma, bile, leukocytes, and mucosal secretions.

17. A kit for distinguishing irritable bowel syndrome from inflammatory bowel disease by testing a fecal sample from a person to be diagnosed, the kit comprising:

one or more microassay plates, each said plate containing immobilized polyclonal antibodies to human lactoferrin;  
enzyme-linked polyclonal antibody to human lactoferrin; and  
enzyme substrate for color development.

18. The kit as recited in claim 17, further comprising purified human lactoferrin as a positive control.

19. The kit as recited in claim 18, further comprising a stop solution for quenching the reaction.

20. A method for monitoring a patient having inflammatory bowel disease, the method comprising:

obtaining a first fecal sample from the inflammatory bowel disease patient at a first time;

determining the concentration of endogenous lactoferrin in said first fecal sample to obtain a first lactoferrin concentration;

obtaining a second fecal sample from the inflammatory bowel disease patient at a second time later than said first time;

determining the concentration of endogenous lactoferrin in said second sample to obtain a second lactoferrin concentration; and

5 comparing said first lactoferrin concentration to said second lactoferrin concentration to evaluate any differences therebetween.

10002242-11401  
TTTT-242200T